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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,593	05/02/2005	Jeffrey D. Johnson	016325-013510US	9564

20350 7590 10/04/2007  
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EXAMINER
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MUMMERT, STEPHANIE KANE

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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10/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/533,593

Applicant(s)

JOHNSON ET AL.

Examiner

Stephanie K. Mummert, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 and 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-17 and 32-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-6, 11-13 and SEQ ID NO:1 and 2 in the reply filed on July 30, 2007 is acknowledged. The traversal is on the ground(s) that the Examiner has not cited any prior art and has not set forth any reason why the claims lack unity. Applicant also asserts that the Office "indicated in the IPER that all claims examined with novel and non-obvious" (p. 2 of remarks). In view of the lack of prior art teaching of a nucleic acid comprising SEQ ID NO:1 or a nucleic acid encoding a protein at least 70% identical to SEQ ID NO:2, the restriction requirement is withdrawn in part. Applicant's suggestion of examining Groups I, IV and VII is acknowledged. The claims to the isolated polypeptide of Group II, the antibody of Group III, the method of diagnosing using the polypeptide of Group V and the method of treating of Group VI remain restricted away because these inventions are distinct from the isolated nucleic acid of Group I and do not require its use in any way and therefore do not meet the requirement for unity of invention.

2. Claims 7-10 and 18-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 30, 2007.

Claims 1-6, 11-17 and 32-40 are pending and will be examined.

***Claim Rejections - 35 USC § 112***

3. Claims 1-3, 5-6, 11-17 and 32-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

**Legal Analysis**

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

These claims are directed to nucleic acids encoding a polypeptide at least 70% identical to SEQ ID NO:2 or where the nucleic acid comprises SEQ ID NO:1 and to isolated nucleic acids capable of 'specifically' hybridizing to a probe comprising SEQ ID NO:1. Therefore, the claims encompass a genus of nucleic acids that are capable of binding, under somewhat stringent conditions as claimed, to a probe comprising SEQ ID NO:1. There are no limitations or instructions provided regarding the minimum number of complementary nucleic acids which meet the limitation of specific hybridization. As currently disclosed and recited, the term may

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read on as little as two consecutive nucleotides and as many as 928 nucleotides, comprising the full length sequence of SEQ ID NO:1.

There are no structural limitations or requirements which provide guidance on the identification of nucleic acids related to SEQ ID NO: 1 or to the polypeptides that are at least 70% identical to SEQ ID NO:2. There are also no functional limitations to claim 6, which provide a function for the sequence which specifically hybridizes to a probe comprising SEQ ID NO:1. Thus, these claims fail on both prongs of the written description analysis since there is no function for the broad structures to define.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

“A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. “

In the current situation, the definition of the protein by percent homology lacks any specific required structure. This is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the specific SEQ ID NO: 2, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim.

**Absence of a representative number of species**

In the current case, the first question is what constitutes a generic claim. The genus of nucleic acids includes any nucleic acid with any degree of homology across the entire nucleic acid sequence of 928 residues comprising SEQ ID NO:1, nucleic acids with as few as 2, 12, or 24 for example, contiguous nucleotides homologous to SEQ ID NO:1, or nucleic acids which encode polypeptides at least 70% identical to SEQ ID NO:2. Thus, the claim reads on a multitude of nucleic acids, including sequences which themselves may not yet be described in the scientific literature. In order to provide a representative number of species, in a genus which contains literally hundreds of billions of different members, the court in Lilly required "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. (Lilly at page 1406)." Lilly continues to note that in other cases, two chemical compounds in a subgenus were insufficient to describe that genus. In the current case, only one species is disclosed, SEQ ID NO:1. These species represent a specific nucleic acid sequence and are not representative of the entire genus.

**Absence of any structure-function relationship for the isolated nucleic acids specifically hybridized to SEQ ID NO:1**

The second issue is whether there is any structure function relationship which correlates a function with a particular structure. This question fundamentally addresses the issue of whether there is any structure which the specification demonstrates is necessarily correlated with the primer or probe functions of the nucleic acid of SEQ ID NO:1. In this case, the answer is no,

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there is no structure given, other than SEQ ID NO:1. Since there is no common structure among the nucleic acids that are specifically associated with the unknown function of the nucleic acid, except for a role as a primer or probe, there is no structure-function relationship between the genus of nucleic acids claimed.

There is a structure given, however, for the polypeptide of SEQ ID NO:2. This polypeptide is an IC-RFX polypeptide and at claim 4 comprises a proline/glutamine rich domain, an RFX DNA binding domain, an RFX B domain, an RFX C domain, a dimerization domain and a serine/threonine domain. Thereby, the claims directed to the nucleic acid (SEQ ID NO:1) encoding the polypeptide of SEQ ID NO:2 meet the structure function relationship.

**The claim scope broadly encompasses any nucleotide sequence with homology to SEQ ID NO:1**

The claims are open to any nucleic acid sequence, whether currently known or not. For this vast genus, only one species is provided. Thus, the conclusion is inescapable that the specification fails to provide a representative number of species in the genus of nucleic acid sequences that share any degree of homology or complementarity across the entire nucleic acid sequence of 928 residues comprising SEQ ID NO:1.

**Conclusion**

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acid sequences other than those expressly disclosed which comprise the genus encompassed by isolated nucleic acids of SEQ ID NO:1 and nucleic acids

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encoding proteins that will have at least 70% homology to SEQ ID NO:2. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 6 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Drmanac et al. (WO01/75067; October 11, 2001 publication date). Drmanac teaches the isolation of nucleic acids and proteins that are useful in the diagnosis and treatment of disorders (Abstract, p. 1).

With regard to claim 6, Drmanac teaches an isolated nucleic acid that specifically hybridizes following at least one wash in 0.2X SSC at 55° C for 20 minutes to a probe comprising SEQ ID NO: 1 (see sequence alignment below, where the nucleic acid has 99% identity across the region of homology and where this sequence would hybridize at ‘high stringency’):

Qy	154	ATGGCCAAGGTCCCGGAGCTGGAAGACACCTTCCTGCAGGCGCAGCCTGCGCCCCAACTG	213
Db	1	ATGGCCAAGGTCCCGGAGCTGGAAGACACCTTCCTGCAGGCGCAGCCTGCGCCCCAACTG	60
Qy	214	TCCCCGGGGATCCAGGAAGACTGCTGTGTGCAGCTCCTGGGCAAGGGCTTGCTAGTCTAT	273
Db	61	TCCCCGGGGATCCAGGAAGACTGCTGTGTGCAGCTCCTGGGCAAGGGCTTGCTAGTCTAT	120
Qy	274	CCGGAAGAAACAGTGTACCTGGCGGCCGAAGGGCAGCCCGGGGGCGAGCAGGGCGGCGGG	333



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Db      121 CCGGAAGAAACAGTGTACCTGGCGGCCGAAGGGCAGCCCGGGGGCGAGCAGGGCGGCGGG 180
Qy      334 GAGAAAGGCGAAGACCCGGAGCTGCCGGGGGCAGTGAAATCAGAAATGCACTTAAACAAT 393
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      181 GAGAAAGGCGAAGACCCGGAGCTGCCGGGGGCAGTGAAATCAGAAATGCACTTAAACAAT 240
Qy      394 GGTAACCTTTTCCTCTGAAGAAGAGGACGCCGACAACCACGACAGCAAAAACCAAAGCAGCG 453
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      241 GGTAACCTTTTCCTCTGAAGAAGAGGACGCCGACAACCACGACAGCAAAAACCAAAGCAGCG 300
Qy      454 GATCAATACCTGTCTCAGAAGAAAACCATCACGCAGATTGTGAAGGATAAAAAGAAGCAG 513
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      301 GATCAATACCTGTCTCAGAAGAAAACCATCACGCAGATTGTGAAGGATAAAAAGAAGCAG 360
Qy      514 ACACAGCTCACGCTGCAGTGGC 535
        |||||||||||||||||
Db      361 ACACAGCTCACGCTGCAGTGCC 382

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With regard to claim 14, Drmanac teaches a method of diagnosing a subject with diabetes or a susceptibility for diabetes, the method comprising detecting in a sample from the subject a polynucleotide that hybridizes to a probe comprising SEQ ID NO: 1 following at least one wash in 0.2X SSC at 55° C for 20 minutes (p. 1, lines 4-6, p. 4, lines 11-18 and specifically p. 5, lines 1-13, where the inventive nucleic acids and proteins are used to detect nucleic acid sequences that can be useful in diagnosis; see also p. 38 and p. 47, where the nucleic acids and proteins are useful for autoimmune diseases, including diabetes).

With regard to claim 15, Drmanac teaches an embodiment of claim 14, wherein the polynucleotide is detected by hybridization (p. 1, lines 4-6, p. 4, lines 11-18 and p. 5, lines 1-13, where the inventive nucleic acids and proteins are used to detect nucleic acid sequences that can be useful in diagnosis and where the nucleic acids can be useful as oligomers, probes or primers in PCR).

With regard to claim 16, Drmanac teaches an embodiment of claim 14, wherein the polynucleotide is detected by amplification of the polynucleotide (p. 1, lines 4-6, p. 4, lines 11-

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18 and p. 5, lines 1-13, where the inventive nucleic acids and proteins are used to detect nucleic acid sequences that can be useful in diagnosis and where the nucleic acids can be useful as oligomers, probes or primers in PCR).

With regard to claim 17, Drmanac teaches an embodiment of claim 14, wherein the nucleotide sequence of the polynucleotide is determined (p. 2, lines 19-22, where the nucleic acid sequence information for SEQ ID NO:1-30368 is provided and necessarily indicates that the sequence of the polynucleotide(s) are determined).

6. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Carnici et al. (Methods Enzymol., 1999, vol. 303, p. 19-44). Carnici teaches a method of isolation of full length cDNA sequences and also teaches the detection and characterization of these sequences.

With regard to claim 6, Carnici teaches an isolated nucleic acid that specifically hybridizes following at least one wash in 0.2X SSC at 55° C for 20 minutes to a probe comprising SEQ ID NO: 1 (see sequence alignment below, where the nucleic acid does not share 100% homology with SEQ ID NO:1, but does share significant homology):

[illegible]

Db	601	AATCCTGTTATCATTTGATATTTTCTGTGCTCTGACTCAATTCTTTATAAGGTTCTTTACA	660
Qy	1135	GATGTACTCATTCTCTGCAACAATGCAAGAAATGCCTGAAAGCTTATTAGCAGACATAAGA	1194
Db	661	GATGTCCTCATTCTCTGCAACAATGCAAGAAATGCCTGAAAGTTTGTTAGCAGATATAAGA	720
Qy	1195	AATTTTGCTAAAAAATGGGAACAGTGGGTTGTTTCATCCTTGGAAAACCTGCCAGAAGCT	1254
Db	721	AATTTTGCTAAAAAATGGGAACAGTGGGTTGTTTCATCCTTGGAAAACCTGCCAGAAGCC	780
Qy	1255	CTAACTGACAAGAAAAATACCTATTGTGCGAAGATTTGTATCTTCTCTGAAACGACAAACA	1314
Db	781	CTCATTGATAAGAAAAATCCCCATTGTTGCGAAGATTTGTATCTTCCCTGAAGCGCAGACACA	840
Qy	1315	TCTTTCTTACATCTTGCCAGATTGCCAGACCAGCTCTCTTTGACCAGCATGTCGTTAAT	1374
Db	841	TCTTTCTTGCATCTTGCTCAGATTGCCAGACCAGCTCTCTTTGACCAGCATGTGGTGAAT	900
Qy	1375	TCTATGGTGTCTGATATTGAAAGGGTTGATTGAACAGCATTGGCTCTCAAGCCCTTCTT	1434
Db	901	GCCATGGTATCTGATATTGAAAAGGTTGACTTAAATAGTATTGGGTCTCAGGCTCTTCTT	960
Qy	1435	ACCATTTCAGGCAGCACAGACACTGAATCTGGTATCTACACTGAACATGACTCTATCACT	1494
Db	961	ACCATATCCAACAGCACAGACACGGAATCTGACATCTACAGTGAACATGACTCTATTACT	1020
Qy	1495	GTGTTCCAAGAACTGAAGGATCTCCTTAAGAAGAATGCCACTGTGGAGGCTTTTATTGAA	1554
Db	1021	GTGTTCCAAGAACTGAAAGATCTCCTTAAGAAGAATGCTACAGTGGAGGCATTATTGAA	1080
Qy	1555	TGGTTGGATACTGTGGTAGAACAGAGTTATTAAAGACCAGCAAAACAAATGGAAGGTCA	1614
Db	1081	TGGTTGGCACTGTGGTAGAGCAGAGTTATTAAAGATGAGCAAAACAAATGGAAGATCT	1140
Qy	1615	TTAAAGAAGAGAGCTCAAGACTTTCTGTTAAAGTGGAGTTTTTTTGGTGTCTGAGTAATG	1674
Db	1141	CTGAAGAAGAGGGCTCAAGACTTTCTGCTCAAATGGAGCTTTTTTGGTGCCCGCTGATG	1200
Qy	1675	CATAATCTCACCTTGAACAATGCATCCAGTTTTGGTCTTTTCATTGATTGCAATGCTT	1734
Db	1201	CATAATCTTACCTTGAACAACGCATCAAGTTTTGGCTCTTCCATCTGATCCGAATGCTT	1260
Qy	1735	CTCGATGAATACATTCTCTGGCCATGGAGACCCAGTTTAATAATGACAAAGAGCAGGAG	1794
Db	1261	CTGGATGAGTACATTCTCTGGCCATGGAGACTCAATTTAACAATGACAAAGAGCAGGAA	1320
Qy	1795	TTACAGAATTTATTGGACAAGTATATGAAGAATTGAGATGCGAGTAAAGCTGCTTTCCT	1854
Db	1321	CTACAGAATTTATTGGACAAGTATATGAAGAACTCGGATGCGAGTAAAGCTGCCTTCACA	1380
Qy	1855	GCTTCTCCGAGTTCATGCTTTCTGGCCAACCGTAATAAAGGGAGCATGGTTTCCAGCGAC	1914
Db	1381	GCTTCCCGAGCTCTTGCTTTCTGGCCAACCGAAATAAGGCTAGCTCACTTGCCAGTGAC	1440
Qy	1915	GCTGTGAAGAATGAAAGCCACGTGGAGACAACCTATCTCCCTCTGCCATCCAGTCAACCT	1974
Db	1441	ACTGTGAAGAACGAAAGCCACGTGGAGACATCCTATGTCCCTCTGCCTTCAGCCAGCCT	1500
Qy	1975	GGAGGCCTAGGCCCTGCTCTGCACCACTTCCCTGCTGGGAACACAGACAACATGCCGCTC	2034
Db	1501	GGAGCCATACCCCTGCTCTGCACCCATTCTCAACTGAGGACACTGATAACATGCCACTC	1560
Qy	2035	ACAGGTCAAATGGAGCTTTCACAGATTGCTGGTCATCTGATGACACCACCATTTCTCCA	2094
Db	1561	CCAGGTCAAATAGAGCTTTCACAAAGTACTGGCCATCTGATGACACCACCGATTTCCTCA	1620
Qy	2095	GCCATGGCAAGCCGAGGAAGTGTATTAAACCAAGGACCAATGCGAGGGAGGCCCCCAAGT	2154
Db	1621	GCCATAGCAAGCAGAGGAAGTGTATTAAACCAAGGGCCAATGGCGAGCAGACCCCCGAGC	1680
Qy	2155	GTGGGCCCAGTACTGTCAGCTCCATCACACTGCTCCACATACCCAGAGCCCATTTATCCC	2214
Db	1681	GTGGGCACAGTTCTCTCAGCTCCAACACATTGCTCAACATATGCAGAACCAATTTATCCT	1740
Qy	2215	ACTCTCCCTCAAGCCAATCATGACTTTTATAGCACCAGCTCTAACTACCAGACTGTGTTT	2274

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Db      1741 ACGCTCTCTCCAGCCAACCACGACTTTTATGGGACCAACTCTAACTATCAGACTATGTTT 1800
Qy      2275 AGGGCACAGCCCCACTCCACATCAGGACTCTATCCTCATCACACCGAGCATGGTCGATGC 2334
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      1801 AGGACACAGTCTCACCTGCATCAAGCCTCTATGCTCACCGTGCAGAGCATGGGCGGTGC 1860
Qy      2335 ATGGCTTGGACTGAACAGCAGCTTTCAAGAGACTTCTTCAGTGGCAGCTGTGCGGGGTCT 2394
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      1861 ATGGCCTGGACTGAACAGCAGCTTTCTAGAGACTTCTTGGTGGCAGTTGTGCTGGGTCT 1920
Qy      2395 CCATATAACTCCCGGCCACCGTCTAGCTATGGCCCATCCCTGCAAGCCCAGGATTCACAC 2454
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      1921 CCATATAATTGTAGGCCACCTTCCAGTTATGGACCATCCACACACACACAAGAGTCACAC 1980
Qy      2455 AATATGCAGTTTTTAAATACAGGAAGCTTCAATTTCTTGAGCAACACAGGAGCTGCCAGC 2514
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      1981 AGCATGCAGGTTTTGAACACAGGAAGCTTCAATTTCTTAGTAATGCAGGAGCTGGCAGC 2040
Qy      2515 TGCCAAGGAGCAACACTGCCTCCTAATTCACCAAATGGATACTATGGAAGCAACATAAAC 2574
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2041 TGCCAAGGGTCAACATTGCCTTCTAATTCTCCCAATGGATACTATGGAACAATATAAAC 2100
Qy      2575 TACCCAGAGTCTCACAGGCTCGGATCAATGGTGAATCAGCACGTTTCTGTGCATCAGCAGC 2634
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2101 TACTCAGAGGCACATAGGCTTGGATCGATGGTGAACCAACATGTTTCAGTCATCAGCAGT 2160
Qy      2635 ATTCGTTCACTGCCCCCTACAGTGACATCCACGATCCACTTAACATTTAGATGACAGT 2694
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2161 GTGCGCTCCCTGCCTCCCTACAGTGATATTCATGATCCACTTAACATTTAGATGACAGC 2220
Qy      2695 GGTAGAAAACAGACCAGCTCGTTTTACACAGACACATCATCTCCAGTTGCATGTGCGAACT 2754
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2221 AGCCGGAAGCAGAAACAACTCGTTTTATGCAGACACATTGTCTCCTGTTGCATGTGCTACT 2280
Qy      2755 CCAGTCCTAGCTTCCAGTTTGCAAACCCCAATTCTTCTCTCATCCCAATGTATGTAT 2814
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2281 ACTGTAGTAGCTTCCAACCTGCAAACCCAGATTCCTTCATCTTCATCCAGTGTATGTAT 2340
Qy      2815 GGAACCTCCAACCATATCCAGCTCAAGAAACCCCTGGACTCCCATGGAACAAGCAGTAGA 2874
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2341 GGAACCTCCAATCAGTATCCAGTGCAAGATAGTCTGGACTCCAATGCAGCAAGCAACAGA 2400
Qy      2875 GAAATGGTGTCTCTTTACCACCTATCAACACTGTGTTCATGGGAACAGCAGCTGGAGGC 2934
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2401 GAAATGGTGTCTCTTTACCACCCATCAACACCGTGTATGGGGACAGCAGCTGGAGAC 2460
Qy      2935 ACTTAAACCAATGTGGGAGG 2957
      ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db      2461 ACTTAAATGAACAATGTAGAATG 2483

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### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carnici as applied to claim 6 above and further in view of Drmanac et al. (WO01/75067; October 11, 2001 publication date).

With regard to claim 14, Carnici teaches a method, the method comprising detecting in a sample from the subject a polynucleotide that hybridizes to a probe comprising SEQ ID NO: 1 following at least one wash in 0.2X SSC at 55° C for 20 minutes (see sequence alignment below, where the nucleic acid does not share 100% homology with SEQ ID NO:1, but does share significant homology).

With regard to claim 15, Carnici teaches an embodiment of claim 14, wherein the polynucleotide is detected by hybridization (p. 43, where the nucleic acid sequences are detected through hybridization with complementary probes).

With regard to claim 16, Carnici teaches an embodiment of claim 14, wherein the polynucleotide is detected by amplification of the polynucleotide (p. 42, where the nucleic acids are tested and detected using PCR amplification).

With regard to claim 17, Carnici teaches an embodiment of claim 14, wherein the nucleotide sequence of the polynucleotide is determined (p. 42, where the clones may be sequenced from the 5' end).

Regarding claim 14, Carnici does not teach the method as specifically diagnosing a subject with diabetes or a susceptibility for diabetes.

With regard to claim 14, Drmanac teaches the detection of nucleic acid as part of a method of diagnosing that may be applied to diabetes (p. 1, lines 4-6, p. 4, lines 11-18 and specifically p. 5, lines 1-13, where the inventive nucleic acids and proteins are used to detect

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nucleic acid sequences that can be useful in diagnosis; see also p. 38 and p. 47, where the nucleic acids and proteins are useful for autoimmune diseases, including diabetes).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have applied the nucleic acids and methods taught by Carnici to methods of diagnosing diseases, including autoimmune diseases like diabetes as taught by Drmanac to arrive at the claimed invention with a reasonable expectation for success. As taught by Drmanac ~~in the~~, "methods for detecting the presence of the polynucleotides or polypeptides of the invention in a sample. Such methods can, for example, be utilized as part of prognostic and diagnostic evaluation of disorders as recited herein and for the identification of subjects exhibiting a predisposition to such conditions" (p. 5, lines 1-5). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have applied the nucleic acids and methods taught by Carnici to methods of diagnosing diseases, including autoimmune diseases like diabetes as taught by Drmanac to arrive at the claimed invention with a reasonable expectation for success.

### ***Conclusion***

Claim 4 is allowable over the prior art. There are no prior art reference that teach an isolated nucleic acid comprising SEQ ID NO:1, which encodes polypeptide of SEQ ID NO:2. The isolated nucleic acid of claim 4, encodes the polypeptide of SEQ ID NO:2 and comprises the domains recited, including a proline/glutamine rich domain, an RFX DNA binding domain (SEQ ID NO:4), an RFX B domain (SEQ ID NO:5), an RFX-C domain (SEQ ID NO:6), a dimerization domain (SEQ ID NO:7) and a serine threonine domain. As there is no teaching in the prior art of

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a nucleic acid encoding a polypeptide encoding these components, the claim is free of the prior art.

Claims 1-5, 11-13 and 32-40 are free of the prior art. There are no prior art references that teach an isolated nucleic acid encoding a polypeptide at least 70% identical to SEQ ID NO:2, or a nucleic acid comprising SEQ ID NO:1. Regarding the nucleic acid of SEQ ID NO:1, the closest reference, Collins et al. (PNAS, 2002, vol. 99, no. 26, p. 16899-16903) was published after the filing date of the priority document, which provides support for SEQ ID NO:1 and 2 (see attached sequence alignments). Regarding a nucleic acid encoding SEQ ID NO:2, the closest reference, Carnici et al. (Methods Enzymol. 1999, vol. 303, p. 19-44) does not disclose or encode a sequence that is at least 70% identical to SEQ ID NO:2 (see attached sequence alignments). Claims 1-3, 5-6, 11-13 and 32-40 stand rejected for other reasons made of record above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert, Ph.D. whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Examiner

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SKM



KENNETH R. HORLICK, Ph.D.  
PRIMARY EXAMINER

10/1/07